

Remarks

Claims 1 and 3-6 are pending in this application. Claims 1 and 3-6 have been amended. Applicants respectfully request entry of the above after-final amendments as they place the claims in condition for allowance or reduce the number of issues for appeal.

Claim 1 has been amended to further recite "***wherein the passage cell line thereof retains NAKT-13 cell line characteristics.***" Support for this amendment appears in the specification and claims as originally filed as read by one-of ordinary skill in the art. Specifically, Applicants submit that one of skill in the art reading the specification and the phrase "NAKT-13 cell line or a passage cell line thereof" would understand that the "passage cell line thereof" would be a passage cell line that retains NAKT-13 cell line characteristics. Furthermore, one of ordinary skill in the art at the time of filing understood that cell lines are routinely reseeded to ensure the cell line and subsequent passage cell lines retain the same intended characteristics.

Claim 3 has been amended to recite "a method of preparing a human pancreatic islet cell prepared by a process comprising: providing the NAKT-13 cell line or a passage cell line thereof of claim 1; excising the hTERT gene and the SV40T gene from the cell line of claim 1 ex vivo; and purifying the resulting cell line." Support for this amendment appears in the specification and claims as originally filed. For example, please see 19, lines 5-18, of the present specification.

Claim 4 has been amended to recite “A method for treating diabetes, comprising: providing the NAKT-13 cell line or a passage cell line thereof of claim 1; excising the hTERT gene and the SV40T gene from the cell line ex vivo; administering an effective amount of the cell line after excision human pancreatic islet cell of claim 3 to a patient in need thereof.” Support for this amendment appears in the specification and claims as originally filed. For example, please see page 13, lines 13-21, and 19, lines 5-18, of the present specification.

Claim 5 has been amended to rewrite the recited “Claim 1” as “claim 1.”

Claim 6 has been amended to recite “the human pancreatic islet cell prepared by the method of claim 3” in order to maintain proper antecedent basis to claim 3 which has been amended to recite a “method of preparing a human pancreatic islet cell.” Support for this claim amendment appears throughout the specification and claims as originally filed. For example, please see page 19, lines 5-18, of the present specification.

Applicants, by cancelling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims cancelled herein or the original claim scope of any claim amended herein, in a continuing application.

No new matter has been added.

In view of the remarks set forth herein, further and favorable consideration is respectfully requested.

- I. **At page 3 of the Official Action, claims 1 and 3-6 remain rejected under 35 USC § 102 (b) as being anticipated by de la Tour et al. (*Molecular Endocrinology*, 2001, 476-483), as evidenced by Halvorsen et al. (*Molecular and Cellular Biology*, 1999, 19: 1864-1870).**

Claims 1 and 3-6 remain rejected under 35 USC § 102(b) as being anticipated by de la Tour et al. as evidenced by Halvorsen et al.

In view of the following, and arguments of record, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP § 2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

In Applicants' previously filed response of October 8, 2008, Applicants' amended claim 1 to recite an "NAKT-13 cell line or a passage cell line thereof" and argued that this recited feature is not taught by the cited references. The Examiner indicates on page 4 of the present Official Action that the present rejection is maintained because the claims "encompass any passage of the NAKT-13 cell line," and because "passages lose the characteristics which distinguish the NAKT-13 cells taught by the prior art and because the claims are drawn to such passages, the claimed invention is anticipated by the art cited above." The Examiner also mentions on page 6 that Richards, Neuroreport 10:i

(1999) is cited as evidence that immortalized cell lines lose their characteristics upon passaging.

However, solely to advance prosecution and without acquiescence or agreement with the rejection, Applicants' have amended claim 1 to recite "[a]n NAKT-13 cell line or a passage cell line thereof **wherein the passage cell line thereof retains NAKT-13 cell line characteristics.**"

In contrast to the presently claimed subject matter, de la Tour et al. is directed to the reversibly immortalized β lox5 cell line. See page 477, column 1, first paragraph. However, de la Tour et al. do not teach or suggest an NAKT-13 cell line or a passage cell line thereof, as presently claimed. Specifically, the β lox5 cell line is unrelated to an NAKT-13 cell line or a passage cell line thereof and is not similar to, or an equivalent of, an NAKT-13 cell line or a passage cell line thereof **wherein the passage cell line thereof retains NAKT-13 cell line characteristics.**

Therefore, Applicants respectfully submit that the presently claimed subject matter is not anticipated by de la Tour et al. because de la Tour et al. do not teach an NAKT-13 cell line or a passage cell line thereof **wherein the passage cell line thereof retains NAKT-13 cell line characteristics.**

Additionally, Halvorsen et al. also do not teach or suggest an NAKT-13 cell line or a passage cell line thereof. Halvorsen et al. merely describe the introduction of simian virus 40 cell large T antigen (SVLT) into human primary cells. Accordingly, Applicants respectfully submit that the presently claimed subject matter is not anticipated by de la Tour et al. as evidenced by Halvorsen

et al. because the cited references do not teach an NAKT-13 cell line or a passage cell line thereof ***wherein the passage cell line thereof retains NAKT-13 cell line characteristics.***

In view of the foregoing, Applicants submit that de la Tour et al. as evidenced by Halvorsen et al. do not teach each and every element of the presently claimed subject matter as required for anticipation under 35 USC § 102(b). Thus, the Examiner is respectfully requested to withdraw this rejection as to claims 1 and 3-6.

II. At page 4 of the Official Action, claims 1 and 3-6 have been rejected under 35 USC § 112, first paragraph, for inadequate written description

Claims 1 and 3-6 are rejected 35 USC § 112, first paragraph, as failing to comply with the written description requirement for allegedly introducing new matter not present in the specification. The Examiner alleges that “the instant claims encompass obtaining the NAKT-13 cell line with any vector encoding hTERT and SV40T.”

In view of the following, and arguments of record, this rejection is respectfully traversed.

First, Applicants respectfully note that the NAKT-13 cell line recited in the claims, and a method of preparing the NAKT-13 cell line, is specifically described in the specification as-filed. See, for example, page 16, line 7, to page 19, line 2.

Second, Applicants respectfully submit that the NAKT-13 cell line has been deposited under the Budapest Treaty. As evidence, Applicants previously

submitted a Declaration of Deposit of Microorganism which indicates that the claimed NAKT-13 cell line has been deposited under the Budapest Treaty with the International Patent Organism Depository, National Institute of Advanced Industrial Science and Technology under the Accession No. FERM BP-08461 on September 4, 2003; and that the claimed biological material will be irrevocably and without restriction or condition released to the public upon the issuance of a patent.

Therefore, it is submitted that the specification, and as evidenced by the biological deposit of the NAKT-13 cell line, provides adequate written description to reasonably convey to one of ordinary skill in the relevant art that the inventors, at the time the application was filed, had possession of the claimed NAKT-13 cell line subject matter within the meaning of 35 USC § 112, first paragraph. Therefore, Applicants submit that the written description requirement under 35 USC § 112, first paragraph, has been met. Accordingly, the Examiner is respectfully requested to reconsider and withdraw this rejection.

Conclusion

In view of the foregoing, Applicant submits that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

THE NATH LAW GROUP



Gary M. Nath
Registration No. 26,965
Susanne M. Hopkins
Registration No. 33,247
Charles D. Niebylski
Registration No. 46,116
Customer No. 20259

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314
Tel: (703) 548-NATH
Fax: (703) 683-8396